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Title of Invention: **EXTRACTS FROM THE MARINE ALGAE UNDARIA, COMPOSITIONS THEREOF AND METHODS OF USE**

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CERTIFICATE OF MAILING OR TRANSMISSION

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November 6, 2006

Commissioner for Patents
P.O. Box 1405
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Dear Commissioner:

Applicants hereby submit a Certified Copy of the Priority Document. This Certified Copy is being submitted in conjunction with a Certificate of Correction in order to perfect the priority claim on the issued Patent according to MPEP rule 201.16.

Please note that a claim for priority was made on the Utility Patent Application Transmittal on June 30, 2003. The priority claim was also stated on the Certificate of Mailing filed with the Application on June 30, 2003. Therefore, in order

to perfect the claim for priority, Applicants hereby submit the enclosed Certified Copy of the Priority Document.

A check is included herewith to cover the fee associated with this correction. If any need for any additional fee is found, for any reason, kindly this a petition therefore and charge any necessary fees to Deposit Account 07-1897.

Respectfully submitted,

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO : 7,056,520

DATED : June 6, 2006

INVENTOR(S) : J. Helen Fitton, Charles Dragar

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Certified Copy of Priority Document is being submitted in order to perfect priority claim.

This application claims priority from Australian Application No. 2002952368, which was filed on October 31, 2002.

MAILING ADDRESS OF SENDER (Please do not use customer number below):
Graybeal Jacson Haley LLP
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Australian Government

Patent Office
Canberra

I, LEANNE MYNOTT, MANAGER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2002952368 for a patent by MARINE RESOURCES PTY LTD as filed on 31 October 2002.

I further certify that the above application is now proceeding in the name of MARINOVA PTY LIMITED pursuant to the provisions of Section 113 of the Patents Act 1990.

WITNESS my hand this
Thirtieth day of May 2006

LEANNE MYNOTT
MANAGER EXAMINATION SUPPORT
AND SALES

EXTRACTS FROM THE MARINE ALGAE *UNDARIA*, COMPOSITIONS THEREOF AND METHODS OF USE

FIELD OF THE INVENTION

The present invention relates to an extract from the marine algae *Undaria* containing galactofucan sulphate and to compositions made therefrom. This invention has particular but not exclusive application for use in the treatment, prevention and prevention of recurrence of viral infections and for illustrative purposes reference will be made to such application.

BACKGROUND OF THE INVENTION

Seaweed is a major part of the diet of many Asian nations. Japanese and Korean populations are the biggest consumers of seaweed products in the world. In recent years evidence has suggested that the high level of seaweed in these diets contributes to a lower incidence of heart disease, diabetes and many other diseases. *Undaria Pinnatifida* constitutes the major part of total dietary intake of seaweed of many Asians. *Undaria* is a member of the Phaeophyceae (brown) class of marine algae, and is native to Japan. It is an annual and generally completes its life cycle over an 8-9 month period.

Brown algal preparations have been used in Chinese and Japanese medicine for many years to treat and prevent a multitude of ailments, and also to maintain good health. Alginates in brown algae act as chelating agents and as absorbents for contaminants such as Strontium 90 (Shandala). Livestock fed on beach cast seaweed is known to show increased health and disease resistance

(Orpin, Saker). Its ingestion actually alters the bacterial spectrum of the gut and it is thought that this may be a possible mechanism for increased immunity and health in both animals and humans seen when dietary levels are high.

Brown marine algae consist mainly of water (90%) in the native state. Polysaccharides are major components and comprise alginates, cellulose and sulphated polysaccharides such as fucoidans. It is thought that fucoidans exist in the plant as part of proteoglycans complexed with other polysaccharides

Fucoidans are long branched chains of sugars and include a substantial amount of fucose. The type of fucoidan, its sulphation, molecular weight, and conformation of sugar residues varies with species of seaweed. For example fucoidan from *Fucus vesiculosis* contains about 90% fucose, while fucoidan from *Undaria* contains 50% fucose and 50% galactose and is known as galactofucan or fucogalactan.

Heparin sulphate, dermatan sulphate and chondroitin sulphate are just three of a plethora of sulphated sugar rich molecules known as glycosaminoglycans (GAGs) that are critical participants in normal physiology. Heparin, for example, is a critical regulatory factor of the blood clotting cascade. Fucoidans are potentially therapeutically important because they mimic these mammalian GAGs.

Heparin sulphate receptors on cell surfaces are critical in many physiological and pathological processes. They are key entry points for viral entry into cells and are also necessary for leukocyte movement into tissues and for metastasis. Algal fucoidan molecules compete successfully for binding sites normally occupied by GAGs and thus inhibit these processes. Many sulphated

polyanions such as the synthetic dextran sulphates, pentosan sulphates, clinically used heparins, and seaweed derived carageenans have all been investigated for ant-viral activity in humans, either systemically or topically (Schaffer DJ *et al.* 2000 *Ecotoxicology and Environmental Safety* 45:208-227, Witvrouw M *et al.* 1997 *Gen Pharmacol* 29:497-511, Luscher-Mattli M, 2000 *Antiviral Chemistry and Chemotherapy* 11(4):249-259). However to date, *Undaria* ingestion has not been clinically assessed for its effects on common coated viruses such as HSV-1 and 2.

Herpes viruses are important human pathogens, causing both primary and secondary infections that range from trivial mucosal ulcers to life threatening disorders in immuno-compromised patients. The Herpes group includes HSV-1, HSV-2, Herpes Zoster (chicken pox/shingles), HCMV (human cytomegalovirus), Epstein Barr Virus (EBV), Herpes 6, 7 (Roseola, post transplant infections) and Herpes 8 (associated with Kaposi sarcoma). The conventional treatment of these infections is with drugs such as ACV that target the viral DNA polymerase.

Whilst these drugs are undoubtedly efficient, they may possibly have side effects, and long-term use has led to the development of resistant viral strains that now comprise 5% of all HSV infections in immuno-compromised patients (Field). Subsequently, finding non-toxic alternatives to these drugs is extremely important for treatment of patients and also potentially as a prophylactic.

Undaria extracts have been shown to have anti-viral effects on HSV-1 *in vitro* (JB Hudson *et al.* 1999 *J. Appl. Phycology* 10;427-434) and also against the EBV (H Ohigashi *et al.* 1992 *Biosci Biotechnol Biochem* 56(6):994-5). Specific molecules responsible for the anti-viral effect were not identified in these earlier studies. *Undaria* fractions have also been shown to have immune stimulating

qualities *in vitro* (BE Shan *et al.* 1999 *Int J Immunopharmacol*, 21(1):59-70) and other brown seaweed fractions have been shown to have immunological effects *in vivo* (H Itoh, *et al.* Anticancer Res 1993 13(6A):2045-52, Schaffer *et al.* 2000, Witvrouw *et al.* 1997).

We have now identified the active component in *Undaria* extracts as galactofucan sulphate which we have found to have antiviral activity. Advantageously, we have discovered an *Undaria* extract containing galactofucan sulphate which is useful in the treatment and/or prevention of viruses.

SUMMARY OF THE INVENTION

The invention in one aspect resides in an extract from *Undaria* including an effective antiviral amount of galactofucan sulphate.

The extract may be obtained from whole plant or any part of the plant, such as the leaves, stem, spores, or a combination thereof. If the plants are harvested prior to maturation suitably the whole plant is used. If the plants are mature suitably the spores may be removed using only the leaves to make the extract. The plant material may be dried prior to the extraction process. The extract may be from any plant in the *Undaria* family. Preferably, the extract is from *Undaria pinnatifida.*

The *Undaria* extract may be made by any suitable method to extract plant material that enables the separation of galactofucan sulphate from the plant material. For example, an acid/water mixture may be used to extract the *Undaria.* Preferably, the acid is sulphuric acid. Suitably, the acid/water extract is then

neutralised and filtrated to remove unwanted components. After filtration, the extract may be used as a liquid or freeze dried.

Galactofucan sulphate may be present in the extract as a heterogeneous mixture of oligomers ranging in molecular weight from 30,000 to 1,200,000. Obviously the amount of galactofucan sulphate in the *Undaria* extract to provide antiviral activity may be dependent on the dosage levels and the intended recipient. Dosage levels of at least 0.5g per day, more suitable 0.9g, of galactofucan sulphate may be a sufficient amount to affect viral infections. It is to be understood that a person skilled in the art would be able to determine sufficient dosage levels of the extract depending on the proportion of galactofucan sulphate in the extract to administer to a person to obtain effective antiviral activity.

Suitably, the extract may have a galactofucan sulphate concentration of at least 10%. Suitably, the extracts of the invention have a galactofucan sulphate concentration of at least 50%, more preferably 60 to 70% or higher.

The extract may be administered orally as a liquid or solid. For example, the case where the extract is administered as a liquid preparation for oral administration, the preparation may take the form of liquid for internal use, shake mixture, suspension, emulsion, syrup or the like. These liquid preparations of the extract of the invention may contain other components ordinarily used, such as additives and preservatives. Alternatively, if composition is applied orally as a solid, it may take the form of a tablet, granules, powder, capsule or like. Solid preparations of the extract of the invention may include any adjuvant or adjuvants which are normally used in the preparation of pharmaceuticals, such as binder,

inclusion, excipient, lubricant, disintegrator, wetting agent, etc. It is to be understood that the extract is not intended to be limited to oral administration.

In one preferred embodiment, spores from *Undaria* may be added to he extract of the invention. For example, the extract may be freeze-dried and ground to a relatively small particle size. This ground extract may then be mixed with similarly ground spores.

The extract of the invention may be used to treat, prevent and/or control viral infection/s.

In a further aspect the invention resides in a method of treating, preventing or controlling a viral infection including administering an extract from *Undaria* including an effective antiviral amount of galactofucan sulphate.

The *Undaria* extract may be any extract as previously described above. The viral infection may be caused by coated viruses including Herpes Viruses and HIV. Preferably, the viral infection treat, prevent and/or controlled by the method of the invention may be HSV-1, HSV-2, Varicella Zoster Virus (in the form of chicken pox or shingles), HCMV, EBV, Herpes 6, Herpes 7 and Herpes 8.

In a still further aspect, this invention resides in a method of extracting *Undaria* including the steps of:

adding acid to harvested *Undaria* plant material, and

collecting and neutralising the filtrate.

The collected filtrate may be dialysed to remove unwanted low molecular weight components. Preferably the *Undaria* plant material is *Undaria pinnatifida.*

DETAILED DESCRIPTION OF THE INVENTION

In order that this invention may be more readily understood and put into practical effect, reference will now be made to the accompanying examples which illustrate preferred embodiments of the invention.

EXAMPLE 1

In one embodiment, the extract of the invention may be made by grinding whole dried plants from *Undaria pinnatifida* to a particle size of less than 1mm. The ground plant material is added to 1%w/v sulphuric acid in a ratio of 1:15w/v in a 316 stainless steel tank. The mixture is stirred for 1 hour and then the solids removed by filtration on a plate and frame filter press. The solids are resuspended in 1%w/v sulphuric acid in the ratio of 1:10 and the extraction procedure is repeated.

The combined filtrates are neutralised with sodium hydroxide to a pH of 6.0. The neutral solution is then subjected to ultra filtration and dialysis using 30,000 cut off membranes to remove low molecular weight components and to concentrate the product. This extraction process may provide an extract that has a galactofucan sulphate content of 60 to 70%.

Suitably the extract is freeze dried and may be used in preparations for treating, preventing and/or controlling viral infections. In another embodiment, the extract is freeze dried and then milled to a particle size of less than 0.4mm. Dried spore bodies from *Undaria pinnatifida* are similarly milled and then mixed with ground extract in a ratio of about 23:2. Dosage levels of about 0.7g of the mixed

milled extract has been demonstrated to be effective in controlling various viral infection.

This mixed extract may be used to form tablets, granules, powder, capsules or like. Solid preparations of the extract of the invention may include any adjuvant or adjuvants which are normally used in the preparation of pharmaceuticals, such as binder, inclusion, excipient, lubricant, disintegrator, wetting agent, etc.

EXAMPLE 2

An extract from *Undaria pinnatifida* was prepared in accordance with the extract process described in Example 1. The extract was freeze dried and mixed with milled spores from *Undaria pinnatifida* to form 560mg capsules containing about 13.25% galactofucan sulphate. The tests described below utilise these capsules and will hereinafter be referred to as *Undaria* extract capsules.

Treatment of patients with active viral infections

Patients were recruited for the study by health practitioners. Patients gave verbal informed consent to the study. Health practitioners monitored the patients' health. There are no known adverse effects related to the ingestion of *Undaria*. No other antiviral medications were taken at the same time as the *Undaria* extract capsules. The duration of the study was from one month to 24 months. Patient ages were from less than 10 years up to 72 years.

Fifteen patients with active herpetic viral infections were given four 560 mg *Undaria* extract capsules per day for ten days as a 'therapeutic dose'. All patients

except subject 14 (primary zoster infection) were suffering repeat outbreaks of known aetiology (See table 1).

All fifteen patients with active herpetic viral infections experienced relief from symptoms. No adverse side effects were noted during the study.

Two patients (subjects 4 and 5) with noncompliant dosage regimes resolved infections in normal time, but noted no spread of lesions (as occurred during previous outbreaks). Reduction in lesion severity and rapid clearance were noted in two patients (subjects 6 and 7), and pain reduction as compared to previous events was noted by two patients (subjects 2 and 14). Two females with genital HSV-2 had persistent lesions which resolved during the course of treatment (subjects 8 and 10).

In two cases of diagnosed EBV, one clear at four and the other by ten days. In the latter patient a chronic sinus condition also cleared (subjects 11 and 12)

Over ten days, faster drying of zoster lesions and increased speed of normal cycle as compared to previous outbreaks was noted by a male patient (subject 14) although no reduction in pain was reported. In an adult male suffering primary zoster (chicken pox) lesions of whole body (subject 15), pain reduction and rapid healing of lesions were noted.

Table 1. Patients with active Herpes infections

Patient	Sex	Age	Virus	Site Infection	Resolution of infection?	If on maintenance, Inhibition of outbreaks?	Comment
1	M	50	HSVI	Orolabial	Yes, no progression to lesion	Yes, inhibition of further outbreaks on maintenance dose >2 years.	Varied dosage, consistent inhibition.

2	F	14	HSV1	Orolabial	Yes, very severe outbreak resolved within course.	N/a	Patient noted rapid reduction in pain.
3	F	72	HSVI prodrome	Orolabial (prodrome) and ocular conjunctiva	Yes, no progression to lesion	Yes, continued inhibition of low grade conjunctival HSVI for three months	Notes improvement in skin condition.
4	M	40	HSVI prodrome	Orolabial	Yes, in normal time.	N/a	Not taken consistently. No benefit noted but no spread of lesion.
5	F	50	HSVI active lesion	Orolabial	Yes,in normal time	N/a	No spread of lesion and pain reduced. Took half dose only.
6.	F	47	HSVI	Orolabial	Yes, reduction in lesion severity	N/a	No recurrence, no spread of lesion.
7.	F	47	HSVI	Orolabial	Yes, rapid clearance compared to previous.	N/a	Post chemotherapy outbreak (breast cancer)
8	F	20	HSVII	Genital	Yes, lesions cleared.	N/a	
9	F	42	HSVII	Genital	Yes. Existing lesion healed.	Yes, inhibition of further outbreaks on maintenance dose 3 mths.	Prior two weekly outbreaks of ACV resistant strain of HSVII.
10	F	23	HSVII	Genital	Yes, chronic lesion healed	N/a	
11	F	17	EBV	systemic	Yes	N/a	Normal blood exam after 4 days course.
12	F	<10	EBV	Systemic	Yes, EBV symptoms	N/a	Three capsules per

					absent at ten days		day Chronic sinus infection also cleared
13	F	85	Zoster (shingles)	Torso	Yes	Yes, inhibition for two months.	Relief from lesions at 4 capsules per day
14.	M	Adult	Zoster (chicken pox)	Whole body sores	Yes	N/a	Pain reduction, rapid clearing of lesions.
15	M	40	Zoster (shingles)	T7,8,dermatome Right side	Yes	N/a	Faster drying of lesions, increased speed of cycle, no change in pain

Treatment of Latent Infections

Six patients with latent HSV-1 or 2 were given two 560mg capsules of *Undaria* extract per day as a 'maintenance dose'. One patient (3) took four 560mg capsules per day.

All six patients on maintenance doses noted inhibition of further outbreaks of infection (Table 2). No adverse side effects were noted during the study.

HSV-1 outbreaks were inhibited in two patients taking a maintenance dose over three months and two years respectively (subject 1 and 2). Low grade HSV-1 associated keratoconjunctivitis in the former patient was also inhibited.

Undaria extract ingestion correlated with inhibition of a previously persistent HSV-2 infection for three months in subject 4. In this patient, the infection was acylovir (ACV) resistant and outbreaks had been apparent on a two weekly basis for over a year. ACV is a nucleic acid inhibitor that prevents viral replication after the virus has entered the cell and is commonly used to treat Herpes.

HSV-2 outbreaks at the genital site were inhibited in two other female patients whilst taking a maintenance dose of two capsules per day, for one month (subjects 5 and 6).

Low grade persistent Herpes zoster (shingles) lesions of the whole torso were inhibited for two months in an elderly patient whilst maintaining a dose of four capsules per day (3).

Table 2: Patients with latent Herpes infections.

Patient	Sex	Age	Virus	Site of infection	Also treated for active infection?	Inhibition of outbreak whilst on maintenance dose?	Comments
1	M	50	HSVI	Orolabial	Yes Existing lesion healed.	Yes, inhibition of further outbreaks on maintenance dose >2 years.	Varied dosage, consistent inhibition.
2	F	72	HSVI prodrome	Orolabial (prodrome) and ocular conjunctiva	Yes, no progression to lesion	Yes, continued Inhibition of low grade conjunctival HSVI for three months	Notes improveme nt in skin condition.
3	F	85	Zoster (shingles)	Torso	Yes	Yes, inhibition for two months.	Relief from lesions requires 4 capsules per day
4	F	42	HSVII	Genital	Yes. Existing lesion healed.	Yes, inhibition of further outbreaks on maintenance dose 3 months.	Prior two weekly outbreaks of ACV resistant strain of HSVII.
5	F	41	HSVII	Genital	No	Yes, inhibition on two capsules per day for 1 month.	Did not take during active lesion outbreak.

6	F	36	HSVII	Genital	No	Yes, inhibition on two capsules per day for 1 month.	Did not take during active lesion outbreak.

In vitro Effects of *Undaria* Extracts on HSV and Human Cytomegalovirus

An *Undaria* extract capsule was mixed 1:40 w/v with distilled water and boiled for 5 minutes. The liquid was filtered through a 0.45μM filter for sterilization and stored at –20°C. An aliquot of the preparation was dried and the weight was obtained to determine the concentration. The concentration used was the dry weight of the dissolved solids present.

Immortalized human fibroblasts, HF cells, were grown in Minimal Essential Media supplemented with glutamine, antibiotics, and 10% foetal bovine serum (FBS). Maintenance medium was supplemented with 1% FBS. Laboratory strains of HSV and HCMV were tested in this study. A stock of each virus was grown in cultured HF cells and aliquots were frozen at –70°C. The titre of each virus was determined by a plaque assay using HF cells in 24-well plates with an agarose overlay.

Herpes viruses were assessed for infectivity of human fibroblasts cells *in vitro*. Inhibition by *Undaria* extract was noted as shown in Table 3.

Table 3: IC50 for *Undaria* extract as measured by infectivity of HSVI, HSV2 and HCMV (human cytomegalovirus) in human fibroblasts.

Herpes virus	*Undaria* extract Capsule mixed 1:40 w/v with water
HSV - 1, strain F	3.1 ug/ml
HSV - 2, strain G	1.6 ug/ml
HCMV, AD169	2.5 ug/ml
HCMV, D16	2.5 ug/ml

In vitro Effects of Extracts on HSV

An *Undaria* extract of the current invention containing galactofucan sulphate was evaluated to determine its antiviral activity against clinical strains of HSV. The extract was significantly more active against clinical strains of HSV-2 than against HSV-1, $p < 0.001$. The mode of action was unknown but preliminary testing indicated the mode of action may be the inhibition of viral entry into the host cell.

HSV-1 strain F and HSV-2 strain G were tested in binding assays and also in post-binding antiviral assay. The viruses were tested in 96-well microtiter plates format using human fibroblast cells. The viruses were inoculated at MOIs of 0.1 and 0.25. For the binding assays, the effective concentration of extract ranged from 128 to 2µg/ml. For the post-binding assays, the concentrations ranged from 4000 to 31µg/ml.

The results of the assay tests are shown in Tables 4 and 5.

Table 4: Inhibition of binding, µg/ml. (MOI = Multiplicity of Infection)

Virus	Strain	*Undaria* Extract
HSV-1, MOI=0.1	F	32
HSV-1, MOI=0.25	F	128
HSV-2, MOI=0.1	G	2.0
HSV-2, MOI=0.25	G	4.0

Table 5: Post-binding inhibition µg/ml. (MOI = Multiplicity of Infection)

Virus	Strain	*Undaria* Extract
HSV-1, MOI=0.1	F	>4000
HSV-1, MOI=0.25	F	>4000
HSV-2, MOI=0.1	G	>4000
HSV-2, MOI=0.25	G	>4000

The extract inhibited HSV from binding to cellular receptors in this *in vitro* assay. There was, however, no post-binding inhibition of HSV by the extract at concentrations up to 4000µg/ml. These results indicate that the extract is effective in inhibiting HSV by blocking attachment and entry into the host cells.

T cell stimulation *in vitro*

T cell mitogenicity was evaluated by chromium uptake. Whole T cell preparations were obtained from buffy coats from human blood samples. They were incubated in RPMI supplemented with 10% heat inactivated foetal calf

serum, 5mM L-glutamine, $5X10^{-5}M$ 2-mercaptoethanol and 30U/ml gentamycin. Incubation for 72 hours was at 5%CO_2, 37°C in 24 well plates. T cell mitogenicity was assessed by radioactive chromium uptake. Cells were incubated with either *Undaria* extract (at 25, 125 and 250 mcg/ml as 1%, 5% or 10% of total culture volume from a stock solution at 2.5mg/ml) or with the known mitogens (PHA) (1mcg/ml) or Concanavalin A (ConA) (1mcg/ml). Each concentration was assessed in triplicate (n=3)

The *Undaria* extract was assessed for effects on whole human T cell preparation *in vitro*. After incubation with the *Undaria* extract or mitogens PHA and ConA, for 72 hours the relative uptake of chromium was assessed as a measure of mitogenicity. The lowest concentration of *Undaria* extract tested (25mcg/ml) exerted a four fold mitogenic effect on T cells, over 50% of the mitogenic potency of the known mitogens PHA (six fold) and ConA (seven fold). Paradoxically, increased concentrations of the whole extract showed decreasing effects on mitogenic activity. This may be accounted for by the increasing physical inhibition due to increased viscosity in the culture media, or the increasing concentration of unidentified inhibitory components present in the extract.

Additional studies illustrated little effect on NK cell activity and no effects on L929 fibroblast growth over 24 or 72 hours (results not shown). There was no bacterial contamination of the *Undaria* extract (results not shown), thus the presence of bacterial lipopolysaccharides (which may also act as mitogens) was ruled out.

Discussion

The studies carried out in Example 2 assessed the effects of *Undaria* extracts containing galactofucan sulphate in patient studies and *in vitro*. The extracts of the invention was ingested by patients suffering active or latent herpes infections. Results indicated firstly, increased rate of healing, and secondly, inhibition of outbreaks in cases of HSV-1, HSV-2, ACV resistant HSV-2, and zoster. There were no adverse side effects noted, and *Undaria* extracts was well tolerated by all subjects. Reduced pain levels were noted in some cases, which may be a result of the increased rate of healing.

A particularly noteworthy result in this study was inhibition of an ACV resistant case of HSV-2. HSV-2 is a sexually transmitted disease of increasing incidence. In part, this is due to the fact that partner transmission may occur during asymptomatic shedding or unrecognised minor outbreaks. Suppressive therapies such as ACV have been tested for their ability to inhibit shedding. However, for long-term use, non toxic alternatives such as *Undaria* extracts may be preferred by patients, who perceive long term conventional drug use as detrimental. In addition, *Undaria* extracts may reduce the generation of resistant strains which arise through prolonged use of drugs such as ACV.

This study shows that ingestion of *Undaria* extracts of the invention is associated with resolution, reduced pain and outbreak inhibition of Herpes virus infections resulting in increased healing rates in patients with active infections. In addition, patients with latent infection remained asymptomatic whilst ingesting the *Undaria* extracts containing galactofucan sulphate. The extracts of the invention inhibited Herpes viruses *in vitro* and was mitogenic to human T cells *in vitro*.

Although the experimental results are only in respect of Herpes Viruses, it is to be understood that any virus which adheres to the cell through a similar mechanism as Herpes Group Viruses would also be inhibited by *Undaria* extracts of the invention.

In the specification the terms "comprising" and "containing" shall be understood to have a broad meaning similar to the term "including" and will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps. This definition also applies to variations on the terms "comprising" and "containing" such as "comprise", "comprises", "contain" and "contains".

It will of course be realised that while the foregoing has been given by way of illustrative example of this invention, all such and other modifications and variations thereto as would be apparent to persons skilled in the art are deemed to fall within the broad scope and ambit of this invention as is herein set forth.

DATED THIS THIRTY-FIRST DAY OF OCTOBER, 2002

MARINE RESOURCES PTY LTD

by

PIZZEYS PATENT AND TRADE MARK ATTORNEYS